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|---------------------------|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/554,167 | 07/11/2000 | THIERRY GICQUEL | 72211/9011 | 6758 |
| 7590 04/20/2004 | | | | |
| DAVID B SMITH | | EXAMINER | | |
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| MILWAUKEE, WI 53202-4108 | | | | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1641 | | |

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/554,167 | GICQUEL ET AL. | |
| | Examiner | Art Unit | |
| | Kartic Padmanabhan | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11,15-17,19-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-11,15-17,19-21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 16-17, 19-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uzan et al. (US Pat. 5,849,247) in view of Berthold et al. (US Pat. 5,048,957), Smethers et

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al. (US Pat. 5,643,535), Honzawa et al. (US Pat. 5,637,874), and Zavislan et al. (US Pat. 5,825,486).

Uzan et al. teaches an automatic immunological assay comprising reaction wells, means for supporting samples to be analyzed, means for supporting reagents, means for taking determined quantities of samples and of reagents and depositing them in reaction wells, means for reading assay results, and means for displacing the wells (col. 1). The reference also teaches means for washing or rinsing the beads in the vessels (col. 2). Furthermore, the reaction modules are formed as single pieces by molding plastics, each comprising eight reaction wells (col. 3). In addition, the reference also teaches the use of a pivoting arm that is used to position reagents or samples (col. 5). A substrate specific to a specific enzyme in the reaction well is deposited in the well, and enzyme interaction takes place, which is followed by reading of the results (col. 7).

Uzan et al. also teach horizontal plates for receiving or supporting the washing means and photometric means. The reference does not teach the specific use of vessels with opaque sides, a chemiluminescent substance as the enzyme in the reaction well, a shutter mechanism, or a light proof shoe.

Berthold et al. teach a specimen rack made of radiopaque material, such that each cuvette, except for a region defined by the lower opening cross section of the through chambers and their upper filling opening, is continuously shielded from scattering radiation from adjacent cuvettes (abstract). The reference does not teach the use of a chemiluminescent substance, a shutter, or a light proof shoe.

Smethers et al. teach a luminometer with reduced sample crosstalk comprising an array of sample wells, a photodetector assembly, and means for moving the sample tray and

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photodetector (abstract). Each well in the array has a structure defining a window through which light can be emitted (col. 2). The reference also teaches the use of luminescence, either chemiluminescence or bioluminescence, as an effective for the determination of a variety of analytes (col. 1). Smethers et al. also teach a photodetector internal-calibration system. This includes a sealed chamber with a light source contained therein, a photosensor, and means for directing the light emitted from the light source to the photodetector when the assembly is positioned at an internal calibration system station. In addition, the reference teaches an external calibration system (col. 2). The reference does not teach the use of a shutter or lightproof shoe.

Honzawa et al. teach a chemiluminescence measuring apparatus comprising a shutter mechanism. The shutter mechanism, when closed, will create a temporary dark chamber that is proof against external light, at which time the photodetector will measure the luminescence. Furthermore, the shutter mechanism includes a rotating hollow chamber, which houses the vessel, a dark box, which can be interpreted as a light-proof shoe, that encompasses the read window, and a photosensing unit, which includes a photomultiplier (col. 2). The rotation of the cylindrical member determines when the shutter opens and closes, and correspondingly when the luminescence is measured. In addition, the dark box portion of the lightproof shoe has an opening that creates an optical path between the vessel and photometric means (col. 2). The references do not teach a light proof shoe directly pressed against the vessel.

Zavislan et al. teach a module comprising a cuvette which holds a liquid sample, which cuvette has an opaque cover pressed against it.

It would have been *prima facie* obvious to one of ordinary skill at the time of the invention to use the opaque vessel of Berthold et al. and the chemiluminescent label of Smethers

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et al. with the vessel of Uzan et al. One would have been motivated to use a chemiluminescent label with the vessel of Uzan et al. because they teach the generic use an enzyme specific for a substrate that produces a detectable signal. Chemiluminescent labels are widely used for this purpose, and would have been an obvious choice for use in the vessel. In addition, one would have been motivated to use a vessel or well with opaque sides to reduce the cross talk or contamination of reading between cells. Since opaque sides limit the emission of light to the top-filling opening, other wells will not be contaminated with the results of adjacent wells.

It would have further been *prima facie* obvious to one of ordinary skill at the time of the invention to use the shutter mechanism and lightproof shoe of Honzawa et al. with the modified vessel of Uzan et al. One would have been motivated to use the shutter mechanism to create a temporary dark chamber to obtain a luminescence reading. Furthermore, a shutter mechanism is well known in the art, as the majority of commercially available photometry instruments utilize these mechanisms to take luminescence readings. In addition, a lightproof shoe can be interpreted as any enclosure or part that is impermeable to light. Once again, this is well known in the art, as all photometers utilize this technique. It would have been obvious to use the calibration system of Smethers et al. with the modified device of Uzan et al. in order to ensure accurate readings for the samples. Calibration is also well known in the art, as background readings need to be subtracted to get true luminescence readings. In addition, it would have been obvious at the time of the invention to arrange the light source such that the filling opening of the wells are also the window for reading the intensity of light, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Finally, it would have been obvious to one of ordinary skill in the art at the time of the

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invention to press the opaque shoe directly against the vessel as in Zavislan et al. because direct, as opposed to indirect, contact ensures a tighter seal, which would keep light out in a more effective and efficient manner.

Allowable Subject Matter

5. Claims 6-11 and 15 are allowed.
6. Claims 6-11 and 15 are allowable over the prior art of record for reasons discussed in the Notice of Allowance mailed on May 3, 2002.

Response to Arguments

7. Applicant's arguments with respect to claims 16-17, 19-21, and 23 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that the combination of Uzan, Berthold, Smethers, and Honzawa do not teach a light proof shoe directly pressed against a planar rim of a vessel, to which the examiner acquiesces; however, Zavislan et al. has been relied upon to cure this deficiency.

Conclusion

Claims 6-11 and 15 are allowed, and claims 16-17, 19-21, and 23 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641




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04/19/04